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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,470	11/21/2002	Claire Marie Fraser	CHIR-0319	2853

7590 12/15/2004
Chiron Corporation
Intellectual Property R440
PO Box 8097
Emeryville, CA 94662-8097

EXAMINER

BASKAR, PADMAVATHI

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/018,470

Applicant(s)

FRASER ET AL.

Examiner

Padmavathi v Baskar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/21/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 and 24-81 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RESTRICTION

1. Applicant's amendment filed on 11/21/02 has been entered. Applicant requests the office to cancel claims 22-23 of the application as filed. Claims 22-23 have been canceled. Claims 3, 5, 11, 15, 16, 18, 19, 20 and 21 have been amended and new claims 25-81 have been entered, Claims 1-21, 24 and 25-81 are pending in the application.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-2 drawn to a method for identifying an amino acid sequence comprising searching for putative open reading frames or protein coding sequences within *N.meningitidis* nucleotide sequences.

Further election of invention required (see Para # 4).

Group II, claims 3 and 25 drawn to a method for producing a protein comprising the step of expressing a protein comprising an amino acid sequence.

Further election of invention required (see Para # 4).

Group III, claim 4 drawn to a method for identifying a protein in a *N.meningitidis* comprising the steps of producing a protein, producing an antibody and determine the antibody binding to protein.

Further election of invention required (see Para # 4).

Group IV, claims 5, 7, 8, 9, 10, 11, 15, 19 -21, 27, 29, 37-57 drawn to a nucleic acid, primer and a composition comprising said nucleic acid.

Further election of invention required (see Para # 4).

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Group V, claims 6, 12-14, 21, 28, 58-60 drawn to a protein and a composition comprising said protein.

Further election of invention required (see Para # 4).

Group VI, claims 18, 21, 33-36 and 61-65 drawn to an antibody and a composition comprising said antibody.

Further election of invention required (see Para # 4).

Group VII, claims 16-17, 30-32 a computer, computer memory, computer storage medium and computer database.

Further election of invention required (see Para # 4).

Group VIII, claims 26 drawn to a method for identifying a protein.

Further election of invention required (see Para # 4).

Group IX, claims 24 and 66-80 drawn to a method of treating a patient using nucleic acid or antibody or protein.

Further election of invention required (see Para # 4).

Group X claim 81 drawn to a method for detecting *N.meningitidis* antigens using antibody. Further election of invention required (see Para # 4).

Group XI claim 82 drawn to a method for detecting *N.meningitidis* antibody using antigens.

Further election of invention required (see Para # 4).

3. The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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The special technical feature of Group I is considered to be a method for identifying open reading frames or protein coding sequences of *N.meningitidis* that requires a computer and program to analyze and compare amino acid sequences.

The special technical feature of Group II is considered to be a method for producing a protein, which comprises expressing a protein comprising an amino acid sequence requiring computer and a program for expression system.

The special technical feature of Group III is considered to be a method for identifying *N.meningitidis* protein comprising the steps of producing a protein producing an antibody and determine the antibody binding to protein that requires a computer and program to analyze *N.meningitidis* strains and antibodies.

The technical feature linking Groups I-III is considered to be methods utilizing products and steps that share no common structure, property and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups I-III

The special technical feature of Group IV is considered to be polynucleotide made up of nucleic acids.

The special technical feature of Group V is considered to be polypeptide, which is made up of amino acids that shares no common structure, property and function with Group IV since polynucleotides contain nucleic acids and do not share the same or a corresponding technical feature with Group V.

The special technical feature of Group VI considered to be antibody that shares no common structure, property and function from Inventions IV-V since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing and do not require each other for their practice.

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The special technical feature of Group VII is considered to be a computer, computer databases which comprises monitor, mouse, screen, key board etc and do not share the same or a corresponding technical feature with Group IV/V/VI.

The technical feature linking Groups VIII-XI is considered to be methods utilizing products that share no common structure, property and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among groups VIII-XI.

Since the special technical feature of the Group I invention is not present in the Group II-IX claims, and the special technical features of the Group II-IX inventions are not present in the Group I claims, unity of invention is lacking.

Pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that where multiple products, processes and methods are claimed, the main invention shall consist of the first invention of the category first mentioned in the claims and the first recited invention of each of the other categories related thereto. Accordingly the main invention (Group 1) comprises a method for identifying an amino acid sequence comprising searching for putative open reading frames or protein coding sequences within *N.meningitidis* nucleotide sequences.

Further pursuant to 37 C.F.R. § 1.475 (d), the ISA/US considers that any feature which the subsequently recited products and methods share with the main invention does not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention. Therefore, the groups of inventions above do not constitute a special technical feature within the meaning of PCT Rule 13.2 and that each of such products and methods accordingly defines a separate invention.

Accordingly Groups I-XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

DISTINCT INVENTIONS

4. For each group of inventions I-XI above, restriction to one of the following sequence is also required under 35 U.S.C. 121 and 372. Therefore, election is required of one of inventions I-XI and one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or one NMB open reading frames or amino acid sequence encoded by any one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or any one of the amino acid sequence encoded by NMB open reading frames. It appears from the sequence listing that applicant has submitted 107 sequences. However, the genome sequence SEQ.ID.NO: 1 appear to contain many sequences because the claims recite the sequences selected from the group consisting of SEQ.ID.NO: 1. Therefore, it is not clear at present what are the sequences within SEQ.ID.NO: 1 are going to be elected by the applicant. Therefore, applicant is advised to clearly specify the start and stop codons and inform the office the same.

The sequences selected from the group consisting of SEQ.ID.NO: 1 or one NMB open reading frames or amino acid sequence encoded by any one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or any one of the amino acid sequence encoded by NMB open reading frames are not so linked as to under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The sequences selected from the group consisting of SEQ.ID.NO: 1 or one NMB open reading frames or amino acid sequence encoded by any one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or any one of the amino acid sequence encoded by NMB open reading frames represent sequences that share no common structure as polynucleotides and polypeptides are not linked by the same the same or a corresponding special technical feature as discussed above so as to form a single general inventive concept. The claimed peptides or polynucleotides share no common special technical feature because the peptides or

polynucleotide have no common structure (i.e., no common sequence) Therefore, where structural identity is required, such as for hybridization or expression of protein or binding of antibody, each sequence appears perform a different function in that peptides elicit an antibody response and nucleic acids encode peptides that specifically bind to an antibody. Thus they share no common structure and function so as to form a single general inventive concept under Rule 13.1. Hence, unity is lacking among the sequences selected from the group consisting of SEQ.ID.NO: 1 or one NMB open reading frames or amino acid sequence encoded by any one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or any one of the amino acid sequence encoded by NMB open reading frames Applicant is required under Restriction is required under 35 U.S.C. 121 and 372 to elect a single sequence disclosed SEQ.ID.NO; 1 or one NMB open reading frame from any group elected.

5. Applicant is required, in reply to this action, to elect a group and one sequence and identify the sequence from the group consisting of SEQ.ID.NO: 1 or NMP open reading frames or amino acid sequence encoded by any one of the sequence selected from the group consisting of SEQ.ID.NO: 1 or any one of the amino acid sequence encoded by NMB open reading frames to which the claims shall be restricted. The reply must also identify the claims readable on the elected invention, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.
6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventor ship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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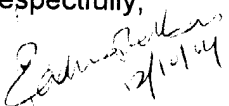
currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventor ship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

8. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

9. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Respectfully,


Padma Baskar Ph.D.